Docket No.: 0171-1287PUS1
(Patent)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent Application of:	Takayuki ONIKI et al.		
Application No.:	10/584,192	Confirmation No.:	3847
Filed:	June 23, 2006	Art Unit:	1612
For:	NONAQUEOUS GEL COMPOSITION FOR TOOTH WHITENING AND TOOTH WHITENING SET	Examiner:	D. SUTTON

DECLARATION UNDER 37 C.F.R. § 1.132

Commissioner for Patents
P.O. Box 1450
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Sir:

I, Takayuki ONIKI, do declare and say as follows:

1. I am a co-inventor of above-identified application.

2. I have read the Final Office Action dated March 17, 2010 in the above-identified application and understand its contents.

3. I have read and understand the contents of the references cited in the March 17, 2010 Office Action, including the references of WO 03/030851 (hereinafter referred to as "Oniki") and U.S. Patent Applic. Public. No. 2001/0007652 (hereinafter "Takeda '652").

4. The present invention is directed to a tooth whitening set for reversibly making tooth look white in the presence of water from saliva comprising a nonaqueous gel composition (i.e., water content of less than 3% by weight of the total amount of the composition and being

free of a peroxide) for tooth whitening and a tool for its application (i.e., tape, sheet or film) which is detachably fitted to teeth while holding it. The nonaqueous gel composition comprises ingredient (A) as a tooth whitening ingredient (in an amount of 50.0 to 99.5 % by weight of the total amount of the composition), ingredient (B) which is a whitening effect substance and dissolves in said tooth whitening ingredient and is precipitated by an aqueous solution of calcium chloride (and is present in an amount of 0.1 to 10 % by weight of the total amount of the composition), and ingredient (C) as a gelling agent and used in an amount of 0.1 to 15 % by weight of the total amount of the composition.

5. I/we conducted testing an actual example in Oniki, as well as testing on modified examples in Oniki and Takeda '652.

Samples of Invention Nos. 1 to 2, Comparison Nos. 1 to 2 and Comparison (Oniki) having formulations as illustrated in the following were respectively prepared.

The Samples were evaluated the effect of tooth whitening immediately after application and endurance of the tooth whitening effect as following manner.

The results are shown in Table 1.

An extracted human tooth which had previously been measured tooth color (L^*0, a^*0, b^*0) was covered with a polyurethane film (20 mm by 20 mm, 50 μm thick) coated with 1.0 g of the gel compositions of Invention Nos. 1 to 2 and Comparison Nos. 1 to 2 (The polyurethane film is DUS2124-CDB from Sheedom Co., Ltd.). The tooth specimen was allowed to stand in a thermostat at 37°C for 1 hour. The polyurethane film was removed and the tooth specimen was cleaned of gel by wiping with tissue paper. After slight water washing, the tooth specimen was measured tooth color (L^*1, a^*1, b^*1), and the value of ΔE 1 was calculated from the following formula. The value of ΔE 1 is regarded as the measure of the tooth whitening effect immediately after application.

Next, the tooth specimen immersed in artificial saliva for 3 hours. The tooth specimen was examined again for color difference (L^*2, a^*2, b^*2), and the value of ΔE 2 was calculated from the following formula. The value of ΔE 2 is regarded as the measure of endurance of the tooth whitening effect.

The color was measure by using a spectrophotometer (CM-2022, from Minolta).

$$\Delta E\,1 = ((L^*1 - L^*0)^2 + (a^*1 - a^*0)^2 + (b^*1 - b^*0)^2)^{1/2}$$

$$\Delta E\,2 = ((L^*2 - L^*0)^2 + (a^*2 - a^*0)^2 + (b^*2 - b^*0)^2)^{1/2}$$

Criterion for rating:

◎: $\Delta E \geq 4.0$

○: $3.0 \leq \Delta E < 4.0$

△: $2.0 \leq \Delta E < 3.0$

×: $\Delta E < 2.0$

Invention No.1

(A) propylene glycol	93 % by weight
(B) Eudragit L100	1 % by weight
(C) hydroxypropyl cellulose	6 % by weight
Total	100 % by weight

The composition is coated on a tape, and is applied to teeth for 3 minutes.

Invention No.2

(A) propylene glycol	89 % by weight
(B) shellac	5 % by weight
(C) hydroxypropyl cellulose	6 % by weight
Total	100 % by weight

The composition is coated on a tape, and is applied to teeth for 3 minutes.

Comparison No.1 (Takeda)

i. The composition of Example 3 in Takeda is applied with brushing for 3 minutes.

ii. The composition of Example 3 in Takeda is coated on a tape, and is applied to teeth for 3 minutes.

Components	wt. %
Silicic acid anhydride	17.0*
Sorbitol (70 %)	63.0
Glycerol	3.0
Propylene glycol	8.0
Shellac	2.0
Sodium carboxymethyl cellulose	0.8
Sodium lauryl sulfate	1.5
Flavor	1.3
Sodium saccharin	0.1
Methyl p-hydroxybenzoate	0.1
Sodium benzoate	0.1
Purified water	3.1
Total	100.0

The total water content of the toothpaste composition of Example 3 in Takeda is 22 wt%.

*Note: The total all component content of the toothpaste composition of Example 3 in Takeda is 98 wt%. Therefore Silicic acid anhydride content was modified 15.0 wt% to 17.0 wt%. Silicic acid anhydride has no influence on the effect of the present invention.

Comparison No.2 (Oniki)

The composition of Example 5 in Oniki is coated on a tape, and is applied to teeth for 3 minutes.

Components	wt. %
Isopropanol	10.0
Propylene glycol	30.0
Sorbitol	10.0
Calcium hydrogen phosphate	10.0
Carrageenan	3.0
Sodium monofluorophosphate	0.7
Cetyl pyridinium chloride	0.01
Flavor	1.2
Saccharin sodium	0.1
Purified water	balance
Total	100.0

The total water content of the toothpaste composition of Example 5 in Oniki is 34.99wt%.

Comparison (Oniki)

(A) propylene glycol	94 % by weight
(C) hydroxypropyl cellulose	6 % by weight
Total	100 % by weight

The composition is coated on a tape, and is applied to teeth for 3 minutes.

Table 1

		Invention		Comparison No.1 (Takeda)		Comparison No. 2 (Oniki)	Comparison (Oniki)
		No. 1	No. 2	i.	ii.		
Tooth Whitening effect	Immediately after application	○	○	×	△	△	○
	Endurance of tooth whitening effect	○	○	×	×	×	×

Based on these results, a superior and lasting whitening effect is achieved for the present invention without using any peroxide, thereby giving an advantage of being a safer whitening composition. Also, teeth look white while at the same time permits teeth to restore their original color in the presence of water (from saliva).

The results shown herein for the present invention are superior and unexpected.

6. I hereby declare that all statements made herein of my own knowledge are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Dated this 11 day of Aug, 2010

By: 鬼木隆行
Takayuki ONIKI